



COMMENTS	-Affix label here-
	Member ID: _____ - _____ - _____
<i>To be completed by Physician Adjudicator</i>	
Date Completed: _____-_____-_____ (M/D/Y)	Central Case No.: _____
Adjudicator Code: _____-_____-_____	Case Copy No.: _____

(For items 1-8, each question specifies "mark one" or "mark all" that apply.)

Complete Q1 - ECG, Q2 - cardiac enzyme, and Q3 - cardiac pain information for the following WHI Extension Study outcomes: Myocardial infarction (MI), coronary death [hospitalized], and coronary revascularization

1. ECG pattern: (Mark the one category that applies best.)

- ₁ Evolving Q-wave and evolving ST-T abnormalities
- ₂ Equivocal Q-wave evolution; or evolving ST-T abnormalities; or new left bundle branch block
- ₃ Q-waves or ST-T abnormalities suggestive of an MI and not classified as code 1 or 2 above
- ₈ Other ECG pattern, ECG uncodable, or normal ECG pattern
- ₉ ECG not available

2. Cardiac enzyme information available?

- ₀ No → **Skip to Question 3 on page 2.**
- ₁ Yes

2.1. Serum creatine kinase (CK): (Mark all that apply.) (Always record % or index if available.)

If CK-MB available:

CK-MB expressed as a % or index: (Record peak results only.)

- ₁ CK-MB at least 2x upper limit of normal for % or index
- ₂ CK-MB greater than upper limit of normal but less than 2x upper limit of normal for % or index
- ₃ CK-MB within normal limits for % or index

CK-MB expressed in units (usually ng/ml): (Record peak results only.)

- ₄ CK-MB at least 2x upper limit of normal for units
- ₅ CK-MB greater than upper limit of normal but less than 2x upper limit of normal for units
- ₆ CK-MB within normal limits for units

If CK-MB not available:

- ₉ Total CK at least 2x upper limit of normal
- ₁₀ Total CK greater than upper limit of normal but less than 2x upper limit of normal
- ₁₁ Total CK within normal limits
- ₉₉ CK result not available

2.2. Troponin lab test. **(Mark the one category that applies best.) (If more than one test was conducted, record the type with the most elevated lab result.)**

- ₁ Troponin C
- ₂ Troponin I
- ₃ Troponin T
- ₄ Troponin, not specified
- ₉ Troponin not available → **Skip to Question 3 below.**

2.2.1 Results **(Mark the one category that applies best.)** Troponin values should be coded using the upper limit of normal (ULN) and not upper limit of indeterminate/indecisive as the reference value. Thus, if 2 cutpoints are given, choose the lower cutpoint for the upper limit of normal.

- ₁ Troponin at least 2x upper limit of normal
- ₂ Troponin greater than upper limit of normal but less than 2x upper limit of normal
- ₃ Troponin within normal limits
- ₉ Other

3. Cardiac pain defined as: an acute episode of pain, discomfort or tightness in the chest, arm, throat or jaw: **(Mark the one category that applies best.)**

- ₁ Present
- ₂ Absent
- ₉ Unknown/Not recorded

Yes ₁ No ₀ 4. Definite, probable, or aborted myocardial infarction (See excerpts from *Table 8.5.1 – Definition of Criteria for Diagnosis of Myocardial Infarction* and *Table 8.5.2 – Algorithm for Enzyme Diagnostic Criteria* on the last page of this form.)

4.1. Date of admission: - - (M/D/Y)

4.2. Diagnosis: **(Mark one.)**

- ₁ Myocardial infarction not occurring as a result of or during a procedure → **Skip to Question 4.3 on the next page.**
- ₂ Myocardial infarction during or resulting from a procedure, i.e., within 30 days of any procedure.
↓

4.2.1. Type of Procedure **(Mark one.)**

- ₁ A myocardial infarction that followed a cardiac procedure within 24 hours (for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion).
- ₂ A myocardial infarction that followed a cardiac procedure within 2-30 days (for example, diagnostic coronary catheterization, percutaneous coronary intervention, CABG, pacemaker insertion, or cardioversion).
- ₃ A myocardial infarction that followed a non-cardiac procedure within 30 days (for example, any elective or emergency non-cardiac vascular procedure regardless of type of anesthesia, or any elective or emergency surgical procedure requiring more than local anesthesia).

4.3 Was a thrombolytic agent administered or emergent* revascularization procedure (e.g., angioplasty or stent) performed? **(Mark one.)**

*An emergent revascularization is conducted within 12 hours of symptom onset; code both here and in Q6. Non-emergent revascularization procedures are coded only under Q6. Examples of thrombolytic agents are streptokinase, reteplase (Retavase), tenecteplase (TNKase), alteplase tPA (Activase).

- ₀ No
- ₁ Yes
- ₉ Unknown

4.4. Was the myocardial infarction fatal? **(Mark one.)**

- ₀ No
- ₁ Yes **(Complete Question 5 below [for hospitalized deaths only] and Form 124 - Final Report of Death.)**

For hospitalized deaths only:

Yes **No** **5. Coronary death (Complete Form 124 - Final Report of Death.)**

- ₁
- ₀

5.1. Date of Death: - - (M/D/Y)

5.2. Diagnosis: _____

Yes **No** **6. Coronary revascularization**

- ₁
- ₀

6.1. Date of Admission/Procedure: - - (M/D/Y)

6.2. **Type of procedure:** Any one of the following procedures aimed at improving cardiac status **(Mark all that apply.)**

- ₁ Coronary artery bypass graft (CABG)
- ₂ Percutaneous transluminal coronary angioplasty (PTCA), coronary stent, or coronary atherectomy

6.3. Second myocardial infarction (MI) (i.e., second MI not already reported in Question 4) occurring as a result of or during the revascularization procedure. **(Mark one.)**

- ₀ No
- ₁ Yes
- ₂ Unknown

- Yes _1 No _0 7. **Carotid artery disease requiring and/or occurring during hospitalization.** Disease must be **symptomatic and/or requiring intervention** (i.e., vascular or surgical procedure).

7.1. Date of Admission: - - (M/D/Y)

7.2. Diagnosis: **(Mark one.)**

- _1 Carotid artery occlusion and stenosis without documentation of cerebral infarction
_2 Carotid artery occlusion and stenosis with documentation of cerebral infarction

7.3. **Carotid artery disease based on** (Hospitalization plus one or more of the following): **(Mark all that apply.)**

- _1 Symptomatic disease with carotid artery disease listed on the hospital discharge summary
_2 Symptomatic disease with abnormal findings ($\geq 50\%$ stenosis) on carotid angiogram, MRA, or Doppler flow study
_3 Vascular or surgical procedure to improve flow to the ipsilateral brain

- Yes _1 No _0 8. **Peripheral arterial disease (aorta, iliac arteries, or below) requiring and/or occurring during hospitalization.** Symptomatic disease including intermittent claudication, ischemic ulcers, or gangrene. Disease must be **symptomatic and/or requiring intervention** (e.g., vascular or surgical procedure for arterial insufficiency in the lower extremities or abdominal aortic aneurysm).

8.1. Date of Admission: - - (M/D/Y)

8.2. Diagnosis: **(Mark the one category that applies best.)**

- _1 Lower extremity claudication
_2 Atherosclerosis of arteries of the lower extremities
_3 Arterial embolism and/or thrombosis of the lower extremities
_4 Abdominal aortic aneurysm (AAA)

8.3. **Peripheral arterial disease based on:** Defined by hospitalization plus one or more of the following: **(Mark all that apply.)**

- _1 Ultrasonographically- or angiographically-demonstrated obstruction, or ulcerated plaque ($\geq 50\%$ of the diameter or $\geq 75\%$ of the cross-sectional area) demonstrated on ultrasound or angiogram of the iliac arteries or below
_2 Absence of pulse by doppler in any major vessel of lower extremities
_3 Exercise test that is positive for lower extremity claudication
_4 Surgery, angioplasty, or thrombolysis for peripheral arterial disease
_5 Amputation of one or more toes or part of the lower extremity because of ischemia or gangrene
_6 Exertional leg pain relieved by rest and at least one of the following: (1) claudication diagnosed by physician, or (2) ankle-arm systolic blood pressure ratio ≤ 0.8
_7 Ultrasonographically- or angiographically-demonstrated abdominal aortic aneurysm
_8 Surgical or vascular procedure for abdominal aortic aneurysm

Responsible Adjudicator Signature

Table 1
Definition of Criteria for Diagnosis of Myocardial Infarction

	Cardiac Enzyme Interpretation (see Table 8.8 below)			
	Abnormal	Equivocal	Incomplete	Normal
ECG Pattern/Symptoms				
Cardiac pain present:				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Definite MI
Equivocal Q wave evolution; or evolving ST-T abnormalities, or new left bundle branch block	Definite MI	Definite MI	Probable MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Definite MI	Probable MI	No MI	No MI
Other ECG, ECG absent or uncodable	Definite MI	No MI	No MI	No MI
Cardiac Pain absent:				
Evolving Q wave and evolving ST-T abnormalities	Definite MI	Definite MI	Definite MI	Probable MI
Equivocal Q wave evolution; or evolving ST-T abnormalities; or new left bundle branch block	Definite MI	Probable MI	No MI	No MI
Q waves or ST-T abnormalities suggestive of an MI and not classified above	Probable MI	No MI	No MI	No MI
Other ECG, ECG absent or uncodable	No MI	No MI	No MI	No MI

Table 2
Algorithm for Enzyme Diagnostic Criteria

Cardiac Enzyme	Abnormal*	Interpretation	
		Equivocal	Normal
Creatine kinase MB fraction (CK-MB)	≥ 2x ULN (as %, index, or units); or “present” without quantification	1-2x ULN (as %, index, or units); or “weakly present”	WNL
Troponin (C, I, or T)**	Troponin ≥ 2x ULN	Troponin 1-2x ULN	Troponin is WNL
Total creatine kinase (CK) (no MB available)	N/A	Total CK ≥ 2x ULN	Total CK is 1-2x ULN or WNL

ULN = upper limit of normal

WNL = within normal limits

* If both CK-MB and Troponin are available, Troponin must be elevated to be considered abnormal, if only CK-MB is available, abnormal levels are enough to code enzymes as abnormal, i.e., WHI considers Troponin as the most accurate indicator of myocardial injury.

** Code Troponin levels using the ULN and not Upper limit of undeterminate/indecisive as the reference value. Thus, if 2 cut points are given, choose the lower cut point for the ULN.